REMARKS

Claims 1-2, 6-12, 14-16, 21-23, 26-29 and 34-38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EP-0-479,582 in combination with either of Eanes (Bone and Mineral 17, pp. 269-272, 1992; or Calcif. Tissue Int. 40, pp. 43-48, 1987) and U.S. 5,039,546 to Chung. Claims 26-30 have been rejected under these references in further view of U.S. 5,310,464 to Redepenning.

First, attention is directed to *In re Hoeksema*, 399 F.2d 269 (CCPA 1968), cited at M.P.E.P. § 2121.02. In this case, the court answered the question whether a claimed compound may be said to be legally obvious when no process for making the compound is shown in the prior art relied upon. The court first stated that "the invention as a whole is the compound and a way to produce it." 399 F.2d at 273 (Underlining added). The court then stated that

> it is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds. 399 F.2d at 274.

After setting forth this standard, the court reviewed an affidavit filed by the applicant which pointed out as a fact that the prior art reference did not disclose a process for producing the different compounds claimed. The affidavit as quoted in the *In re Hoeksema* case did not include any experimental data. The court concluded that the affidavit stated facts which were legally sufficient to overcome the position of the Patent Office as to the legal effect under section 103 of the prior art reference. In particular, the court noted that the affidavit pointed out that there is no indication in the

reference that the process used to produce the prior compounds could be used to produce applicant's compounds. The court concluded that "since we are of the view that the method for making the compounds is an integral part of the 'invention as a whole' which we must consider under section 103, we conclude that the burden of going forward with proofs to support its position as to obviousness of the claimed invention shifted to the Patent Office upon [applicant's] filing of the [named] affidavit." 399 F.2d at 275.

Now turning to the present application, the Declaration provided with the Request for Continued Examination makes it clear that the process of the prior art references could not produce the invention of claim 1. In particular, it was explained that the processes of Eanes would puncture the walls of the vesicle thereby making the containment of a pharmaceutically active agent within the vesicle impossible.

Under the standards of the *In re Hoeksema* case detailed above, the present Applicant has met its burden of overcoming the obviousness position of the Patent Office. In other words, the present Applicant has provided sufficient evidence that a method for making the compounds is not obvious from the prior art. Furthermore, there is no requirement in the *In re Hoeksema* case that the Declaration must include experimental data as suggested in the Office Action. Given that the method for making the claimed vesicles is an integral part of the 'invention as a whole' evaluation and that the prior art does not teach a method for making the claimed vesicles, it is submitted the claimed vesicles are not obvious from the prior art.

Thus, it is respectfully submitted that the invention of claim 1 (and remaining pending claims that depend thereon) is not obvious over EP-0-479,582, the Eanes

references, Chung or Redepenning taken in any combination as these references fail to provide a method for making the claimed vesicles which is an integral part of the 'invention as a whole' obviousness evaluation.

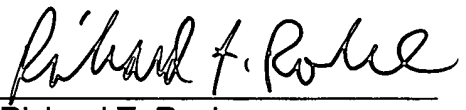
Conclusion

It is submitted that the application is in condition for allowance.

No other fees are believed to be needed for this amendment. However, if additional fees are needed, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,
Jan Tadeusz Czernuszka *et al.*

Dated: April 7, 2004

By: 

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